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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/734,221	12/11/2000	Dan R. Littman	1049-1-004n2	6077

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Klauber & Jackson
411 Hackensack Avenue
Hackensack, NJ 07601

EXAMINER

LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/734,221

Applicant(s)

LITTMAN ET AL.

Examiner

Bao Qun Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 33-40 and 61-74 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 33-36, 38-40, 61-69 and 71-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 70, 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date 02/28/2006
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION**RCE**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/20/2005 has been entered. The RCE follows:

Response to Amendment

The amendment filed on 12/20/2005 has been acknowledged. Claims 37 and 74 have been amended. Claims 1-26, 33-40, 61-74 are pending before the examiner. Claims 1-26, 33-36, 38-40, 61-69 and 71-73 are withdrawn from the consideration. Claims 37, 70 and 74 are considered.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 37, 70 and 74 are still rejected under 35 U.S.C. 112, first paragraph under the same ground as stated in the previous Office Action, because the specification, while being enabled for having a method of screening an HIV-1 macrophage tropic (HIV M-tropic) fusion inhibitor with cells expressing both CD4 and CCR5 in the presence of M-tropic HIV-1 infection or a virus pseudotyped with a full-length of HIV M-tropic envelope protein, does not reasonably provide enablement for a method of screening any or all HIV fusion inhibitor with a cell that only expresses CCR5 in the presence of any

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virus pseudotyped with any or all kind of M-tropic envelope, wherein an inhibitor identified by the method can be used for prevention of AIDS. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. Applicants traverse the rejection and submitted that claim 37 have amended as a method of identifying an agent that inhibits an HIV infection rather than preventing HIV-1 infection, the rejection should be withdrawn.

4. Applicants' amendment as well as argument has been respectfully considered; however, it is not persuasive because this amendment does not overcome the rejection for the scope of method reads on identifying agent with a virus pseudotyped with any kind of Macrophage-tropic envelope protein.

5. However, the state of art does not teach that any macrophage-tropic envelope protein can bind to CCR5 and induce fusion as pointed out in the previous office action (page 9, paragraph 19) mailed on December 21, 2004. There are so many viruses that can infect human macrophage via its envelope protein binding to the target cells, such as Dengue virus (DV) in light of the disclosure by Chen Yapin et al. (J. Virol. 1996, Vol. 70, No. 12, pp. 8765-8772, see abstract). Monocytes/macrophages (MO/M Φ) are the major and primary targets for DV infection known in the art (Please see Moreno-Altamiano et al. Scand. J. Immunol. 2004, Vol. 60, pp. 631-638, see 2nd paragraph of 631 and Chen Yun-Chi et al. (J. Virol. 1999, Vol. 73, No. 4, pp. 2650-2657). However, the receptor for said infection is not mediated by the CCR5 as evidenced by Chen Yun-Chi et al. (See page 2650 and 2652). They found that the presence of high level of CC chemokine RANTES unable to suppress the DV infection, and LPS markedly suppressed DV infection of primary human MO/M Φ directly and specifically when it was added to cultures prior to or together with, but not after, viral adsorption. The inhibitory effect of LPS was direct and specific and was not mediated by LPS-induced secretion of cytokines and chemokines such as tumor necrosis factor alpha, interleukin-1 β (IL-1 β), IL-6, IL-8, IL-12, alpha interferon, MIP-1 α , and RANTES. Moreover, the specification does not provide sufficient evidence to support this broad scope of invention. Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claim 37 is still rejected under 35 U.S.C. 102(a) as being anticipated by Cocchi et al. (Science 1995, Vol. 270, pp. 1811-1815) in light of Moriuchi et al. (J. Immunol. 1997, Vol. 159, pp. 5441-5449) on the same ground as stated in the previous Office Action.

8. Applicants traverse the rejection in the response filed on October 17, 2005. Applicants admitted that the Examiner correctly outlines these conditions as settled by the Federal Circuit citing the review article of Feit et al. (2003, J. Pat. Trade Off. Soc., Vol. 85, No. 1, pages 5-21) when the examiner use the prior art by Cocchi et al. to reject the claims. However, Applicants still argue with following points;

9. 1). Cocchi et al. do not teach or suggest all of the limitations of claim 37 as currently amended, either expressly or inherently, i.e. Cocchi et al. do not teach or suggest a method of selecting an agent for possible use in the treatment of the HIV-1 infection caused by a macrophage-tropic HIV virus, wherein the entry for the macrophage-tropic virus into the target cells is mediated by CCR5;

10. 2). Cocchi et al. do not teach or suggest that chemokines such as RANTES, MIP-I alpha or MIP-I beta prevent the virus from fusing with the cells mediated by CCR5 recited in the currently amended claims;

11. 3). The CCR5 is a co-factor for the Monocyte tropic HIV was not known at the time when Cocchi et al. reference was published.

12. Interview with attorney Veronic Mallon and Applicant Dan R. Wittman regarding to this inherent rejection was also conducted on Feb. 28, 2006 in the presence of Supervisor examiner James Housel.

13. Applicants' argument has been respectfully considered; however, it is not found persuasive because the rebottle of this argument has been clearly discussed in the previous office actions in that Cocchi et al. teach method uses same type of cell

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inherently expresses CCR5, same kind of virus – macrophage tropic HIV-1 virus, and same active step of putting a test reagent into the test system comprising both Macrophage-tropic HIV-1 virus and target cell inherently expressing CD4 and CCR5 that applicants cited in the claimed method. Because the CC chemokines disclosed by Cocchi et al. competitively bind CCR5 with the macrophage-tropic HIV envelope protein definitely, and consequently inhibit said virus infection via the inhibiting the fusion process inherently and certainly regardless whether the CCR5 was known as M-tropic HIV co-receptor at the time Cocchi et al. publish the paper. Because Feit et al. states that it is irrelevant whether it was apparently at the time of filling the application in question.

14. Therefore, the rejection is remained.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BAOQUN LI, MD
PATENT EXAMINER
Bao Qun Li

03/02/2006

